




Is the use of ultra-low insufflation pressure safe and feasible in robot assisted radical prostatectomy

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ABSTRACT

Objective: Current innovations in minimally invasive surgery include using ultra-low insufflation pressure with the aim of improving peri-operative and short-term clinical outcomes. Despite an exponential increase in the use of robotic technology, there remains limited literature supporting the use of ultra-low pressure during robotic surgery. We performed a feasibility study of ultra-low-pressure robot-assisted laparoscopic radical prostatectomy (RARP).

Material and methods: Prospective data related to standard pressure (15 mm Hg) RARP (Group 1) and ultra-low-pressure (6 mm Hg) RARP (Group 2) were collected and compared to assess the peri-operative and short-term outcomes.

Results: Outcome data of 112 consecutive patients (56 in each group) were collected. Mean age, pre-operative prostate specific antigen, body mass index, and performance status were similar in both groups. Mean console time was shorter in ultra-low-pressure RARP group (125 minutes) than in standard pressure RARP group (138 minutes) ($p=0.016$). Furthermore, there was no significant difference in console time or estimated blood loss between these 2 groups for patients with RARP and lymph node dissection. No patients from either group required conversion to an open procedure or received a peri-operative blood transfusion. None of the patients in either group developed post-operative complications or needed readmission.

Conclusion: Our study has demonstrated that ultra-low-pressure RARP is a practical and safe option, and it supports the routine practice of ultra-low-pressure RARP with slow adaptation in other complex robotic surgeries, such as robotic cystectomy for bladder cancer.

Keywords: Safety; urologic surgical procedures; urology; prostatectomy; prostatic neoplasms

Introduction

In the late nineteenth century, George Kelling's pioneering work on canines regarding intra-abdominal minimally invasive surgery led to the first laparoscopic procedure being performed on a human being by Dr. Jacobaeus in 1910.^[1] Extensive work throughout the 1950s and 1960s involving different insufflation gases and their physiological consequences led to the introduction of the first reliable abdominal pressure monitoring device designed by Kurt Semm in 1966.^[2] This advancement in the ability to accurately monitor pressure led to the now widely adopted laparoscopic standard pressure of 15 mm Hg that provided excellent visibility and manageable intra-operative physiological consequences when compared with open surgery.^[3]

There is a large amount of published evidence showing that laparoscopic surgery performed at lower insufflation pressures significantly improves intra-operative physiological parameters and reduces post-operative pain. This improves patient experience and can result in the improved economic performance of the procedures. With the advancement of technology and the growing number of robotically assisted procedures, there is a need to assess the feasibility of ultra-low-pressure robotic surgery.

Robot-assisted laparoscopic radical prostatectomy (RARP) is a gold standard treatment for prostate cancer. There is a paucity of available evidence regarding the feasibility of this procedure at low insufflation pressures despite a body of evidence suggesting improved post-operative

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patient parameters such as reduced pain and length of stay (LOS).^[4] Therefore, we compared and analyzed RARP at a standard pressure of 15 mm Hg against an ultra-low pressure of 6 mm Hg.

Material and methods

A total of 112 consecutive RARPs for organ-confined prostate cancer performed by a single surgeon at a tertiary center were included in the study. Of the 112 consecutive RARPs, the first 56 operations were performed at a standard pressure of 15 mm Hg with subsequent adaptation to an ultra-low pressure of 6 mm Hg for the second cohort of 56 patients. All patients provided informed consent for the procedure. This data was registered within our institution as an audit and therefore no formal ethical committee approval was required.

All procedures were performed by a single consultant surgeon using a step-wise technique with no variation in the method. All patients received a single intravenous dose of antibiotic before induction in the anesthetic room. Patients were positioned in a standard steep Trendelenburg position with 20° of tilt. An open cutdown approach was performed to gain access followed by a standard pressure to facilitate port insertion and robot arm docking using the AirSeal device (CONMED Corporation, Utica, NY, USA) maintains a consistent intra-abdominal pressure despite suction, smoke evacuation, or instrument changes. Once entry had been deemed appropriate and safe, the pressure was maintained at 15 mm Hg for Group 1 and the pressure was reduced to 6 mm Hg for Group 2. In both groups, the entirety of the operation was performed at this pressure, including management of the dorsal venous complex. Bilateral extended lymph node dissection (LND) was performed according to risk stratification using the Memorial Sloan Kettering Cancer Center nomograms. Patients were monitored overnight in the neighboring post-operative care unit and discharged the next day as a standard practice if deemed clinically appropriate.

The data were collated prospectively by the operating surgeon using the nationally adhered to BAUS pro-forma that is used to

audit national operative outcomes. The prospectively collected data for 2 cohorts were compared with regard to demographics and were analyzed to assess intra-operative console times, estimated blood loss, and length of hospital stay. The feasibility of the procedure has been defined as no statistically different outcomes in favor of standard pressure settings. Intra-operative blood loss was assessed from the suction collection system, and any volume of irrigating fluid used was removed from the total volume. Subgroup analysis has been performed to assess whether LND affected the outcomes.

Statistical analysis

Data distributions were assumed non-normal, and all statistical differences on the data have been assessed by the Mann–Whitney test using “GraphPad Prism Version 8.2.1 (GraphPad Software 2365 Northside Dr.Suite 560 San Diego, CA 92108).

Results

Baseline demographics of 2 groups were compared (Table 1). None of the patients in either group needed intra-abdominal pressure adjustments, and the entirety of the procedures were performed at pre-designated pressures. Median age (62 years vs. 66 years), body mass index (BMI; 27 kg/m² vs. 28 kg/m²), ASA grade, and performance status were comparable. Group 2 patients had a higher prostate specific antigen (PSA) level (6.4 ng/ml vs. 9 ng/ml; $p=0.0011$), but T staging was comparable for both cohorts.

The median (range) console time of Group 1 was 136.5 minutes (120–195) and that of Group 2 was 120 minutes (106–145). Despite the ultra-low pressures, the median procedure time was shorter in the second cohort, although statistically not significant ($p=0.0525$). Intra-operative blood loss was significantly less in Group 2 with the mean blood loss being 35 ml lesser than that of Group 1 (145 ml vs. 181 ml; $p=0.0029$). None of the patients in either group required a blood transfusion. Furthermore, mean hospital stay was 0.1 days shorter in ultra-low–pressure group, suggesting early post-operative recovery (Table 1).

The pathological parameters such as Gleason score, T Stage, prostate volume, and margin status were comparable between the groups. The mean lymph node yield was higher in the ultra-low–pressure group (19 nodes vs. 13 nodes).

We performed a subgroup analysis of patients undergoing LND (Table 2). The ultra-low–pressure LND group had a median console time of 144 minutes versus 156 minutes in the standard pressure group ($p=0.465$). Similarly, estimated blood loss was significantly lower in the ultra-low–pressure group than in the standard pressure group (165 ml vs. 203 ml; $p=0.0036$).

Main Points:

- There is a strong body of evidence showing that laparoscopic and robotic surgery performed at reduced insufflation pressures improves post-operative pain scores and intra-operative cardiorespiratory parameters.
- Robotic surgery performed at ultra-low insufflation pressures does not increase procedural time or increase intra-operative blood loss.
- Operating at ultra-low pressure is technically feasible, does not impair the visual outcomes, and does not affect histopathological outcomes.

Table 1. Results table (demographics, operative outcomes & histopathological details)

	Insufflation Pressures		p-value
	13-15mmHg	6mmHg	
Patient demographics			
Number	56	56	0.539
BMI (kg/m³)	27.0 (25.0-29.0)	28.0 (25.0-29.0)	
Age	62 (55-70)	66 (56-71)	
Preoperative PSA (ng/mL)	6.4 (5.0-8.7)	9.0 (6.7-12.5)	0.001
ASA grade	2	2	
Performance status	1	1	
Intra-operative details			
	Mean (range)	Mean (range)	0.053
Console Time (mins)	136.0 (120.0-205.0)	120.0 (106.0-195.0)	
Estimated Blood Loss (mL)	181 (112.5-200.0)	145 (100-160)	
Transfusion requirement	0	0	0.003
Post-operative results			
	Median (mean)	Median (mean)	0.604
Length of Stay (days)	1 (1.3)	1 (1.2)	
Same Day Discharge	1 (1.8)	1 (1.8)	
Post-op Clavien 3-4 complications	0	0	
30 day re-admission rate	0	0	
Pathological status			
	n (%)	n (%)	0.217
T2	42 (75)	47 (84.7)	
T3a	14 (25)	8 (14.5)	
T3b		1 (1.8)	.156
Positive Margins	14 (25)	16 (29.6)	
Mean weight of gland (g)	46.9 (24-115)	48 (26-106)	
Mean nodal yield (n)	13 (2-39)	19 (6-44)	.067
Gleason sum score (n)			
6	2	5	
7	50	41	
8	2	4	
9	2	6	
BMI: body mass index; PSA: prostate specific antigen; ASA: American Society of Anesthesiologists;			

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Table 2. Sub-group analysis of patients undergoing bilateral extended lymph node dissection

			p-value
BPLND sub group			
	13-15mmHg	6mmHg	
console time (mins)	156 (140-205)	144 (125-195)	0.465
<i>Mean</i> blood loss (mls)	203	165	0.004
No BPLND sub group			
	13-15mmHg	6mmHg	
console time (mins)	123 (120-180)	116 (106-145)	0.367
<i>Mean</i> blood loss (mls)	166	135	0.079
BPLND: bilateral pelvic lymph node dissection;			

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Discussion

The physiological changes that are observed during laparoscopic surgery are a result of patient positioning and an increase in intra-abdominal pressure owing to pneumoperitoneum (PNP).^[4] The establishment of PNP leads to direct mechanical effects on the patient. Cranial movement of the diaphragm together with muscle paralysis leads to the compression of the lung parenchyma, decreased tidal volumes, and increased ventilator airway pressure requirements.^[5, 6] Biochemical respiratory effects are observed with the use of carbon dioxide (CO₂), which is a highly soluble gas resulting in a relative hypercapnia that requires a mechanical compensation in the form of hyper-ventilation that must be accounted for in patients with poor pre-operative pulmonary function tests.^[7, 8] The use of CO₂ PNP also has well-documented physiological effects on the cardiovascular system by IVC compression and reduced pre-load. The subsequent hypercapnia leads to metabolic acidosis and activation of the renin-angiotensin system, which may affect blood pressure and cardiac contractility.^[9, 10] Fortunately, the clinical effects of these changes are often limited owing to intra-operative management by the anesthetic team.

Given the above understandings, a body of evidence has developed showing that PNP achieved at lower pressures improves intra-operative cardiovascular and respiratory parameters but also provides significantly improved post-operative pain (POP) scores. Given the potential benefits and an aging population with more cardiovascular morbidity, it is important to assess the feasibility of ultra-low-pressure surgery within the context of different urological procedures.

A systematic review and meta-analysis by Hua et al.^[11] comparing laparoscopic cholecystectomies at low (10 mm Hg) and standard pressures (15 mm Hg) found statistically significant reductions in POP and LOS in all timeframes in favor of the low-pressure group. Topçu et al.^[12] performed a randomized trial assessing POP after laparoscopic gynecological cases and found significant reductions in pain in the low-pressure group (8 mm Hg); however, longer post-operative stays were also observed. A randomized controlled trial of 76 patients undergoing upper urinary tract laparoscopic surgery using 3 different insufflation pressures demonstrated significant reductions in POP in the low-pressure group (10 mm Hg)^[13]. This finding has further been reinforced by Bhattacharjee et al.^[14] with a randomized trial comparing 80 patients. Improvements in intra-operative cardiovascular parameters have been recorded with the use of reduced pressures.⁹

A prospective single center study performed by La Falce et al.^[15] on 53 consecutive patients undergoing RARP at a pressure of 8 mm Hg found improvements in multiple intra-operative car-

diovascular parameters but did not include post-operative outcome data. A randomized trial by Umar et al.^[16] concluded that high intra-abdominal pressure owing to CO₂ insufflation is associated with more fluctuations in hemodynamic parameters and increased peritoneal absorption of CO₂ compared with low intra-abdominal pressure. Whether the cardiovascular changes observed using low pressure confer an actual clinical benefit is yet to be established with several other studies suggesting no significant effect on post-operative outcomes.^[17, 18] Despite this, the extent of hemodynamic changes associated with the creation of PNP depends on the intra-abdominal pressure attained, volume of CO₂ absorbed, patient's intravascular volume, ventilator technique, and surgical conditions.^[19] Therefore, it is important, particularly in morbid patients, that small gains are acquired through each of these parameters to optimize outcomes.

The feasibility of RARP procedure at an ultra-low pressure has been confirmed by the data presented. Despite the apprehension of difficult surgery and excessive bleeding, the whole procedure was performed at ultra-low pressure of 6 mm Hg. We have demonstrated, even in patients with higher BMI, that ultra-low-pressure RARP could be adapted safely. Contrary to the traditional anxiety of a prolonged procedure and reduced visibility with reducing PNP, our study showed that intra-operative console time and estimated blood loss were significantly lower in the ultra-low-pressure group. Similarly, our study showed shorter mean hospital stay that may be attributed to early cardiovascular, respiratory, and general recovery from surgery. Furthermore, there was no increased readmission rate in the ultra-low-pressure group supporting the safety and feasibility of this approach.

An area of concern that may be raised using ultra-low pressures is in those patients who are undergoing LND. The complexity of the dissection and proximity to major lower limb vessels may be made more difficult by reduced visibility.^[20] Once again, in our study, we did not find any difference in console times or blood loss between the 2 groups undergoing RARP with LND suggesting the extended benefits of ultra-low-pressure surgery in complex procedures involving LND. Anecdotal information provided by the operative surgeon indicates that the use of ultra-low-pressure PNP does not increase the complexity of the operative process, and in particular, when managing the dorsal venous complex, good visibility is maintained at low pressures.

Owing to the perceived technical challenges of operating within ultra-low-pressure fields, some authors have raised a concern regarding the potential for inferior oncological outcomes. However, within this series a marginally higher positive rate was observed in terms of the use of ultra-low pressure, and it is consistent with the national estimates and with other RARP series. A retrospective analysis by Sachdeva et al.^[21] of 592 cases had an overall positive margin rate of 30.6% from a United King-

dom tertiary referral center. One factor to be considered when interpreting the higher rate in the ultra-low-pressure group is the higher baseline median PSA of 9 in the ultra-low-pressure group and the increased detection of higher Gleason score of patients in this cohort.

The improvement in physiological intra-operative cardiovascular and respiratory parameters has been shown to contribute to a shorter length of hospital stay. Reduced intra-abdominal pressures improve POP scores, which is consistent within the current literature. This series has shown the feasibility of performing RARP at low pressure with statistically significant improvements in LOS and intra-operative blood loss. The complexity of the procedure is not increased, and the visibility is not affected. Overall, oncological outcomes are consistent with other series.

To conclude, our prospective series support the fact that RARP performed at ultra-low pressures is a safe and feasible method with no observable negative short-term outcomes. Currently, within our institution all robotic procedures being performed, including cystectomy, are at ultra-low pressures and a larger series using a varied group of robotic procedures will give further evidence to support this hypothesis.

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